K060708

# 510(k) Summary

JAN 24 2007

**Applicant:**

Somnomedics GmbH & Co.KG
Nonnengarten 8
Kist, Germany D-97270
Phone: +49 93 06 98 23 0
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**US Contact:**

M Squared Associates, Inc.
Cherita James
719 A Street, NE
Washington DC 20002
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**Date submitted:** January 11, 2007

**Proprietary Name:** Somnomedics SOMNOscreen

**Common Name:** Ventilatory Effort Recorder

**Classification Status:** Class II per regulations §868.2375

**Product Codes:** MNR

**Establishment Registration Number:** Will be obtained prior to US distribution of the device.

**Manufacturing/ Distribution Address:**

Somnomedics GmbH & Co.KG
Nonnengarten 8
Kist, Germany D-97270

**Predicate Devices:** SleepScreen/ApnoeScreen Cardio (K021138), Compumedics Siesta System (K003175)

**Device Description:**

The SOMNOscreen is a portable physiological signal recording system intended to be used to record, display, monitor, print and store biophysical events to aid in the diagnosis of neurologic and sleep disorders. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is NOT designed to be used in a Life Support situation.
This device is not designed for use on patients with cardiac pacemakers.

**Indication for Use:** The SOMNOscreen is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.

**Intended Use:**

The SOMNOscreen is indicated for use in the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of Neurological and Sleep Disorders.

**Summary of Technological Characteristics:**

The system provides up to 28 channels for data acquisition; 10 AC Channels, 8 Referential and 2 Differential, 11 Respiratory and AUX Channels, 7 Internal Channels (SPO2, Pulse Rate, Plethysmogram, Body Position, Light, Patient Marker, Thorax/Abdominal Respiratory Effort)

The SOMNOscreen is available in 6 different configurations. All configurations include a Compact Flash Card and Reader, Li ION Batteries, (2000mAh) with 1 x Battery Charger, a Carry Bag for housing the SOMNOscreen and Sensors, Instruction Manuals and the DOMINO software for Initialization, Data Transfer and Analysis.

**Summary of Nonclinical Testing:**

Performance testing was conducted to confirm compliance to device specifications; all functions were verified to operate as designed. Measured parameters met required ranges and accuracies. Testing to the international standards for electrical safety and electromagnetic compatibility were

performed. The SOMNOscreen was found to be compliant with the requirements of these standards.

**Summary of Clinical Testing:**

A validation study of 25 patients evaluated with the SOMNOscreen, the predicate Sleepscreen from Viasys (K021138, originally Jaeger) and the manual scored Polysomnography demonstrates that the clinical performance of the SOMNOscreen when used as intended in the targeted patient population, is equivalent to the predicate Sleepscreen and the manual scored Polysmnography cleared for the evaluation of the recording, displaying, monitoring, printing, and storage of biophysical parameters for the purpose of assisting in the diagnosis of sleep-related respiratory disorders.

**Conclusion**

SOMNOMEDICS Somnoscreen has the same principles of operation and similar technological characteristics as the previously 510k cleared predicates. The differences do not present new issues of safety or effectiveness.

Based on extensive performance testing and a comparison to the predicate devices, the SOMNOMEDICS Somnoscreen is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness. Additionally, the device has identical indications to the predicate devices and the labeling of the device is consistent both with FDA's guidance as well as current medical practice.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Somnomedics GmbH & Company KG
C/O Ms. Cherita James
Regulatory Consultant
M Squared Associates, Incorporated
719 A Street, NE
Washington, DC 20002

JAN 24 2007

Re: K060708
Trade/Device Name: SOMNOscreen
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: January 11, 2007
Received: January 12, 2007

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

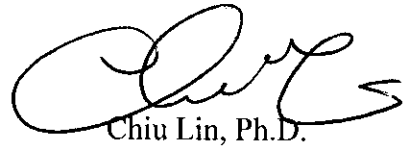
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number: **K060708**

Device Name: SOMNOscreen

Indications For Use: The SOMNOscreen is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K060708